Summary Report

Testosterone cypionate

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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Prepared by:

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REVIEW OF NOMINATIONS

Testosterone cypionate (UNII code: M0XW1UBI14) was nominated for inclusion on the 503B Bulks List by David Smith, AnazaoHealth Corporation, the Outsourcing Facilities Association (OFA), Empower Pharmacy, Rebecca Mitchell, and the Specialty Sterile Pharmaceutical Society (SSPS). It was nominated to treat hypogonadism, low testosterone levels in men and women, and gender reassignment via intramuscular or subcutaneous injection (strengths ranging from 50-200mg/mL) or topical gels, creams, and solutions of unspecified strengths. Testosterone cypionate was recommended as a combination product with testosterone propionate (see Table 7 for nominated combination formula).

Reasons given for nomination to 503B Bulks List are as follows:

- Patient sensitivity/allergies to cottonseed oil excipient in commercial product compared to grapeseed or sesame oil used in compounded product.
- Greater concentration needed than commercially available.
- Manufacturer backorder.
- It is relatively unsafe to expose the direct compounding area to hundreds of vials or ampules and hundreds of aseptic manipulations during the compounding of a typical batch size for an outsourcing facility; compounding from bulk is more safe and efficient.
- Commercially available finished products have an inherent variance in potency creating an uncertain final concentration for the new product.
- Use of state of the art equipment, like the SKAN isolator technology, requires the use of bulk starting materials.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of testosterone cypionate products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA) and approval status provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for testosterone cypionate; name variations of testosterone cypionate were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient(s); strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing testosterone cypionate. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through March 6, 2019. The search included a combination of ("testosterone cypionate"[TIAB] OR "testosterone ciponate"[TIAB]) AND (hypogonad*[TIAB] OR endocrin*[TIAB] OR treat*[TIAB] OR therap*[TIAB] OR clinical[TIAB]) AND "humans"[MeSH Terms] AND English[lang] NOT autism. Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Testosterone cypionate is a component of an FDA-approved product; as a result, articles were excluded if testosterone cypionate was utilized as the FDA-approved product or in the same concentration and formulation as the FDA-approved product. Articles were considered relevant based on the identification of a clinical use of testosterone cypionate or the implementation of testosterone cypionate in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

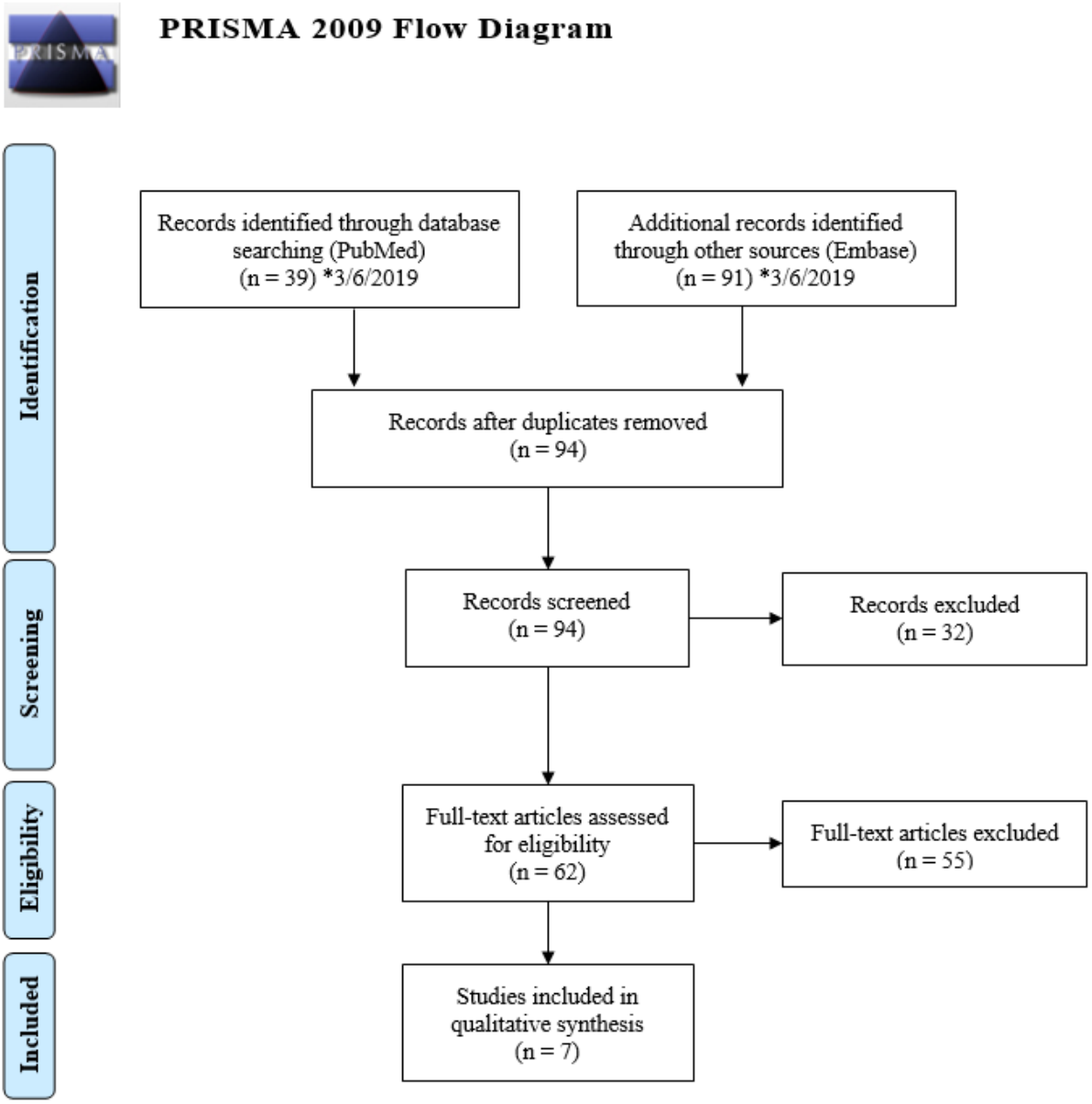
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for testosterone cypionate use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of testosterone cypionate compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses:* The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indications from the nominations and the results of the literature review, eight (8) medical specialties that would potentially use testosterone cypionate were identified: endocrinology, naturopathy, neurology, obstetrics and gynecology, oncology, primary care, psychiatry, and urology. Semi-structured interviews were conducted with subject matter experts within this/these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. Two (2) experts were contacted for interviews, of which two (2) accepted and zero (0) declined interviews. One (1) interview was recorded and transcribed via ©Rev.com, while the other was not recorded due to equipment failure. QSR International's Nvivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for endocrinology, naturopathy, neurology, obstetrics and gynecology, oncology, primary care, psychiatry, and urology, identified from the nominations, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to twelve associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Due to the identification of additional substances relevant to these associations, testosterone cypionate was included on a naturopathy survey with dehydroepiondrosterone (DHEA), estradiol, estradiol cypionate, estriol, estrone, medroxyprogesterone, pregnenolone, progesterone, testosterone, and testosterone propionate.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Naturopathy	American Association of Naturopathic Physicians (AANP)
Primary Care	American Academy of Environmental Medicine (AAEM)

Table 2. Associations that declined participation

Specialty	Association	Reasons for declining
Endocrinology	American Association of Clinical Endocrinologists (AACE)	Declined, "Endocrinologists are not generally in the compounding space."
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Neurology	American Academy of Neurology (AAN)	Failed to respond
Obstetrics and Gynecology	American College of Obstetricians and Gynecologists (ACOG)	Declined, survey was not approved for distribution
Oncology	American Society of Clinical Oncology (ASCO)	Failed to respond
Primary Care	American College of Physicians (ACP)	Failed to respond
	American Academy of Family Physicians (AAFP)	Failed to respond
Psychiatry	American Psychiatric Association (APA)	Declined, "We…have not received any information on psychiatrists using compounded products."
Urology	American Urology Association (AUA)	Declined, "Our physicians are inundated with surveys and I'm afraid you won't be able to get the information you need."

CURRENT AND HISTORIC USE

Summary of background information

- Testosterone cypionate is available as an FDA-approved product (see Table 3).
- Testosterone cypionate is not available as an over the OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for testosterone cypionate.
- Testosterone cypionate is available in Canada and New Zealand (see Table 4).

Table 3. Currently approved products – US[a]

Active Ingredient	Concentration	Dosage Form	ROA	Status	Approval Date[b]
Testosterone cypionate	100, 200mg/mL	Injectable	Injection	Prescription	Before 01/01/1982

Abbreviation: ROA, route of administration.
[a]Source: US FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book)
[b]If multiple approval dates, then earliest date provided.

Table 4. Currently approved products – select non-US countries and regions[a]

Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
				Country	Status	Approval Date
Testosterone cypionate	100mg/mL	Solution	Intramuscular	Canada	Prescription	12/31/1953
Testosterone cipionate			Injectable	New Zealand	Prescription	12/31/1969

Abbreviation: ROA, route of administration.
[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, ROA and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or ROAs similar to those requested in the nominations. See Methodology for full explanation.

Summary of literature review

- Total number of studies included: 7 studies (3 descriptive and 4 experimental studies).
- Most of the studies were from the US (3 studies), followed by the UK (2 studies).
- No studies were found to support the nominated combination formula.
- There was no most common indication in the US or non-US countries.
- Dosing ranges per ROA:
    - Intramuscular (250-400mg/28 days)
- No compounded products were identified from any studies.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1-3]	3
Experimental[4-7]	4
Observational	0

Table 6. Number of studies by country

Country	Number of Studies
Brazil[3]	1
Israel[6]	1
UK[4,5]	2
US[1,2,7]	3
	Total US: 3 Total non-US Countries: 4

Table 7. Number of studies by combinations

	Combination Formula	Number of Studies
Nominated	Testosterone cypionate 300mg/mL / Testosterone propionate 20mg/mL	0

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Cluster headache[2]	200-400mg	–	–	Intramuscular	1-3 doses
Metastatic castration-resistant prostate cancer[7]	400mg/28 days	–	–	Intramuscular	–
Spinal cord injury[1]	–	–	Pellet	Subcutaneous	6 months

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Erectile dysfunction[4,5]	250mg/month	–	–	Intramuscular	6-12 months
Dysthymia[6]	200mg/10-12 days	250mg/mL	–	Intramuscular	40-48 days
Hypogonadism[3]	250mg/28 days	–	–	–	–

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 10. Compounded products – US

No compounded products from reported studies

Table 11. Compounded products – non-US countries

No compounded products from reported studies

Summary of focus groups/interviews of medical experts and specialty organizations

Two (2) interviews were conducted. For one interview, the audio recording malfunctioned and as a result the interview was not recorded.

Table 12. Overview of interviewees

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Testosterone Cypionate	Interview Summary Response
END_01	MD	Endocrinology and Metabolism Internal Medicine	Academic medical institution	Yes	• Uses testosterone cypionate, but typically in an FDA-approved product
OBG_01	MD	Obstetrics and Gynecology	Academic medical institution	Not specified	• Does not specify use

Abbreviation: MD, Doctor of Medicine

Use of testosterone cypionate

- One reported not seeing any need or reason in practice to mix testosterones into a combination product. Uses compounded testosterone products but tries to avoid it due to concerns about supraphysiological hormone levels.

Need for "office stock"

- Neither would stock compounded testosterone in the office.
    - One gave two reasons: lack of use and concern about stability.
    - Another used FDA-approved testosterone products 98% of the time and there was no need to administer in office.

Supplemental information

- One interviewee provided references regarding the serious health and safety risks associated with the use of compounded "bioidentical" hormone products in menopausal women, as well as scientific, positional statements, and other publicly available documents nominating hormones to the demonstrably difficult to compound list.[8-18]
    - Information included a statement on the use of testosterone therapy in women,[10] position statements from the Endocrine Society regarding the use of compounded bioidentical hormones,[12,13,16] and position statements from the North American Menopause Society regarding the use of hormone therapy in menopausal patients.[14,15]

Summary of survey results

Table 13. Characteristics of survey respondents [55 people responded to survey.[a]]

Board Certification	MD	ND	No Response
Endocrinology, Diabetes and Metabolism	0	1	0
Family Medicine	1	0	0
Fellow of the American Board of Naturopathic Oncology	0	1	0
Integrative Medicine	1	0	0
Naturopathic Doctor	0	6	0
Naturopathic Physician	0	9	0
Obstetrics and Gynecology	1	0	0
No Board Certification	1	4	0
No Response	0	0	38

Abbreviations: MD, Doctor of Medicine; ND, Naturopathic Doctor.
[a]Some respondents reported more than one terminal clinical degree or board certification.

Table 14. Types of products used, prescribed, or recommended

Types of products	Respondents, n (N=24[a])
Compounded	5[b]
FDA-approved	5
Over-the-counter	0
Dietary	0
Unsure	0
No response	17

[a]Out of 55 respondents, 24 reported using, prescribing, or recommending multiple types of testosterone cypionate.
[b]Three (3) respondents used in combination (see Figure 2 below for specifics).

Figure 2. Compounded combinations reported in the survey

Active ingredients in combination products:

- "Testosterone cypionate 200mg/mL / Testosterone propionate 20mg/mL"
- Testosterone, anastrozole

Table 15. Compounded use of testosterone cypionate in practice[a]

Indication	Strength	Dosing Frequency	Dosage Form	ROA	Duration of Treatment	Patient Population
Andropause Hypogonadism	100mg	Weekly	Oil	Intramuscular	Ongoing	Aging males
Male gonadal failure that has failed topical therapy	Variable	1-2x/week	Sterile solution	Intramuscular	Ongoing	Middle aged/older males
Testosterone deficiency	100-150mg/week	2x/week	Injection	Subcutaneous	Years	Males
	200mg/mL	1-2x/week	Injectable	Intramuscular	As needed	Males
				Subcutaneous		
	10-15mg/week	2x/week	Injection	Subcutaneous	Years	Women
Transgenderism	100mg	Weekly	Oil	Intramuscular	Ongoing	Aging males

Abbreviation: ROA, route of administration.
[a]Four (4) respondents

Table 16. Indications for which testosterone cypionate is considered a standard therapy[a]

Indication	Standard Therapy			
	Compounded, n (N=5)	Non-Compounded, n (N=5)	Unsure, n (N=0)	No response, n (N=17)
Hypogonadism, male gonadal failure	2	1	0	0
None	0	1	0	0
Other[b]	1	0	0	0
Testosterone deficiency	2	0	0	0
Transgenderism	1	0	0	0
No response	0	0	0	17

[a]Some respondents reported more than one indication.
[b]"not that many"

Table 17. Reasons for using compounded product instead of the FDA-approved products

Theme	Reasons
Availability	• "Also, testosterone can be compounded with anastrozole eliminating the need for a separate anastrozole tab prescription."
Cost	• "Price is lower"
Quality	• "Patient preference, purity of product (limited inactive ingredients)" • "Better"
Safety	• "FDA-approved product is in cottonseed oil, which is regulated as an industrial product (highly sprayed with pesticides/herbacides)" • "Compounded products usually made from sesame or grapeseed oil which are a much cleaner plant crop (compared to cottonseed, which often has pesticides and other chemicals in the plant)."
Sensitivity	• "Patients tolerate grapeseed oil better than FDA approved agent."

Table 18. Change in frequency of compounded testosterone cypionate usage over the past 5 years

	Respondents, n (N=5)
No - use has remained consistent	2
Yes - I use it LESS often now[a]	1
Yes - I use it MORE often now[b]	2

[a]One (1) respondent wrote "not needed."
[b]One (1) respondent wrote "seeing more older men."

Table 19. Do you stock non-patient specific compounded testosterone cypionate in your practice?

	Respondents, n (N=5)
No	5
Yes	0

Table 20. Questions related to stocking non-patient specific compounded testosterone cypionate

No survey respondents provided information for this section

CONCLUSION

Testosterone cypionate (UNII code: M0XW1UBI14) was nominated for inclusion on the 503B Bulks list to treat hypogonadism, low testosterone levels, and gender reassignment surgery via injectable and topical routes. Out of the national medical registers that were reviewed, testosterone cypionate is available in the US, Canada, and New Zealand.

From the literature review conducted, there was no most prevalent indication for the use of testosterone cypionate. No studies supported the nominated combination form or reported using compounded testosterone cypionate.

Interviewees did not see any benefit in using compounded hormonal products over commercially available FDA-approved products.

Out of specialty organizations that were approached for survey participation, only the AANP and AAEM agreed to participate. Out of 55 respondents, 24 reported using testosterone cypionate in practice. Three reported use of the nominated compounded combination product. Four out of the five respondents who reported using compounded testosterone cypionate in practice elaborated on the indications, which support the ones nominated, with similar reasoning behind their choices.

APPENDICES

Appendix 1. References

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Appendix 2. Survey instrument

Testosterone cypionate

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **testosterone cypionate**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871

Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Testosterone cypionate

Q1 What type(s) of product(s) do you use, prescribe, or recommend for **testosterone cypionate**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for testosterone cypionate? Please... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for testosterone cypionate? Please... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for testosterone cypionate? Please... = Compounded drug product

Q2 Please list any conditions or diseases for which you use compounded **testosterone cypionate** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3 Do you use compounded **testosterone cypionate** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded testosterone cypionate as a single agent active ingredient, or as one activ... != Combination

Display This Question:

If Loop current: Do you use compounded testosterone cypionate as a single agent active ingredient, or as one activ... = Combination

Q4 In which combination(s) do you use compounded **testosterone cypionate**? Please check all that apply.

- ☐ Testosterone cypionate 200mg/mL / Testosterone propionate 20mg/mL
- ☐ Other (please describe)_____

Page Break

Q5 For which, if any, diseases or conditions do you consider compounded **testosterone cypionate** standard therapy?

_____

Q6 Does your specialty describe the use of compounded **testosterone cypionate** in medical practice guidelines or other resources?

_____

Q7 Over the past 5 years, has the frequency in which you have used compounded **testosterone cypionate** changed?

- ○ Yes - I use it **MORE** often now (briefly describe why)_____
- ○ Yes - I use it **LESS** often now (briefly describe why)_____
- ○ No - use has remained consistent

Q8 Why do you use compounded **testosterone cypionate** instead of any FDA-approved drug product?

_____

Q9 Do you stock non-patient-specific compounded **testosterone cypionate** in your practice location?

- ○ Yes
- ○ No

Skip To: End of Block If Do you stock non-patient-specific compounded testosterone cypionate in your practice location? = No

Page Break

Display This Question:

If Do you stock non-patient-specific compounded testosterone cypionate in your practice location? = Yes

Q10 In what practice location(s) do you stock non-patient-specific compounded testosterone cypionate? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11 How do you obtain your stock of non-patient-specific compounded **testosterone cypionate**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe)_____

Q12 Why do you keep a stock of non-patient-specific compounded **testosterone cypionate**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe)_____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone cypionate? Please check a... = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone cypionate? Please check a... = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded testosterone cypionate? Please check a... = Other (please describe)

Page Break

Q13 For which, if any, diseases or conditions do you consider **testosterone cypionate** standard therapy?

_____

Q14 Does your specialty describe the use of **testosterone cypionate** in medical practice guidelines or other resources?

_____

End of Block: Testosterone cypionate

Start of Block: Background Information

Q15 What is your terminal clinical degree? Please check all that apply.

- ☐ Doctor of Medicine (MD)
- ☐ Doctor of Osteopathic Medicine (DO)
- ☐ Doctor of Medicine in Dentistry (DMD/DDS)
- ☐ Naturopathic Doctor (ND)
- ☐ Nurse Practitioner (NP)
- ☐ Physician Assistant (PA)
- ☐ Other (please describe)_____

Q16 Which of the following Board certification(s) do you hold? Please check all that apply.

- [ ] No Board certification
- [ ] Allergy and Immunology
- [ ] Anesthesiology
- [ ] Cardiovascular Disease
- [ ] Critical Care Medicine
- [ ] Dermatology
- [ ] Emergency Medicine
- [ ] Endocrinology, Diabetes and Metabolism
- [ ] Family Medicine
- [ ] Gastroenterology
- [ ] Hematology
- [ ] Infectious Disease
- [ ] Internal Medicine
- [ ] Medical Toxicology
- [ ] Naturopathic Doctor
- [ ] Naturopathic Physician

- [ ] Nephrology
- [ ] Neurology
- [ ] Obstetrics and Gynecology
- [ ] Oncology
- [ ] Ophthalmology
- [ ] Otolaryngology
- [ ] Pain Medicine
- [ ] Pediatrics
- [ ] Psychiatry
- [ ] Rheumatology
- [ ] Sleep Medicine
- [ ] Surgery (please describe)_____
- [ ] Urology
- [ ] Other (please describe)_____

End of Block: Background Information